510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K092408

Submitter / Distributor:

OCT 1 4 2009

Rapid Response Solutions, LLC
N 10623 County Road A
Athelstane, WI 54104

Contact Person:

Jorge Millan, PhD
Email: jmillan@hiatec.org

Manufacturer:

MiniMax Manufacturing Co.,LTD
1F No.144,Lane 101,Sec.3,Jiayuan Rd.
Shulin City,Taiwan(R.O.C.)
TEL:(886)-2-2680-5276 FAX:(886)-2-2680-5275

Date Prepared:

July 29, 2009

Name of the device:

- **Trade/Proprietary Name:** Rhythm of Life
- **Common Name:** CPR Aid (Metronome) – CPR Timer
- **Classification:** 21 CFR 870.5200 CPR Aid (Metronome) Class III

Legally Marketed Predicate Device:

K003937	CPR Ezy-Pad by Medteq Innovations Pty LTD
K071321	Pocket-CPR by Bio-Detek Incorporated
K954692	CPR Prompt by County Line LTD
N/A	LyfeTymer

Device Description:

The Rhythm of Life by Rapid Response Solutions, LLC, is a pocket-sized metronome designed to assist both professional rescuers and trained lay rescuers in providing high quality cardiopulmonary resuscitation. This device is designed in accordance with the latest American Heart Association guidelines for CPR. The Rhythm of Life provides three distinctly different tones and visual feedback to prompt the rescuer to compress the patient's chest, ventilate the patient, and reassess the patient's condition every two minutes. The metronome will allow the rescuer to enter the type of patient that is being resuscitated along with other pertinent information, and then outputs proper resuscitation rates and ratios for that specific patient. Both professional and lay rescuers will benefit from additional guidance provided by the Rhythm of Life as it promotes adherence to the American Heart Association's guidelines and therefore improves the quality of patient care. The device is neither life supporting nor life sustaining.

Statement of Intended Use:

The Rhythm of Life is a visual and audio timing device assisting individuals trained in CPR to provide effective resuscitation by conforming to the guidelines promoted by the American Heart Association in the field, clinical, and hospital settings. The Rhythm of Life is also intended for use by those in an educational setting who are in the process of learning CPR.

Testing:

Testing was conducted to validate and verify that the Rhythm of Life met all design specifications and was substantially equivalent to the predicate devices. Testing was performed to demonstrate compliance with the following applicable standards:

ANSI C63.4 & 47 CFR Part 15, Subpart B; EN60601-1-2 : 2001+A1:2006 CISPR 11 : 2003; IEC61000-4-2 : 1995+A1:1998+A2:2000; IEC61000-4-3 : 2006 and IEC61000-4-8 : 1993+A1:2000.

Conclusion:

The Rhythm of Life Metronome is as safe, as effective, and performs as well to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 14 2009

Rapid Response Solutions, LLC
c/o Jorge Millan, Ph.D.
Official Correspondent
601 West 20 Street
Hialeah, FL 33010

Re: K092408
Rhythm of Life
Regulation Number: 21 CFR 870.5200
Regulation Name: Aid, Cardiopulmonary Resuscitation
Regulatory Class: Class III
Product Code: LIX
Dated: July 31, 2009
Received: August 6, 2009

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K092408**

Device Name: Rhythm of Life

Indications for Use:

The Rhythm of Life is a visual and audio timing device assisting individuals trained in CPR to provide effective resuscitation by conforming to the guidelines promoted by the American Heart Association in the field, clinical, and hospital settings. The Rhythm of Life is also intended for use by those in an educational setting who are in the process of learning CPR.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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